

New Antimicrobial Agent Pathway

Pharmaceutical
Company

Submits "New Drug Approval" (NDA)
request packet to FDA
-clinical outcome data
-microbiological data
-breakpoints
-QC ranges
-other

If FDA approved

Therapeutic details provided in
pharmaceutical product labeling;
includes FDA breakpoints

Submits condensed version of NDA
request packet to CLSI
-clinical outcome data
-microbiological data
-breakpoints
-QC ranges
-other

If CLSI approved

Testing details and CLSI breakpoints
provided in laboratory testing "reference
standards"CLSI M2, M7 and M100

Testing to establish FDA
breakpoints done using CLSI
"standard reference methods"

Diagnostic Manufacturer

Submits diagnostic AST device
performance data to FDA

If FDA approved

Testing details provided in diagnostic
AST device product labeling;
includes FDA breakpoints

Diagnostic AST device performance
data is based on manufacturer
demonstrating that their device
produces results comparable to
results produced with CLSI
"standard reference methods"